### PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY JÖNSSON, Hans-Peter Von Kreisler Selting Werner WRITTEN OPINION OF THE Deichmannhaus am Dom INTERNATIONAL PRELIMINARY Bahnhofsvorplatz 1 EXAMINING AUTHORITY 3 O. JUNI 200 5 50667 Cologne ALLEMAGNE (PCT Rule 66) (day/month/year) 29.06.2005 Applicant's or agent's file reference **REPLY DUE** within 2 month(s) 041748wo HPJ from the above date of mailing International application No. International filing date (day/month/year) Priority date (day/month/year) 03.07.2003 PCT/EP2004/007215 02.07.2004 International Patent Classification (IPC) or both national classification and IPC B32B27/08, B32B27/30, B32B27/32, B32B27/36, A61J1/00 Applicant B. BRAUN MEDICAL AG et al. The written opinion established by the International Searching Authority: 1. considered to be a written opinion of the International Preliminary Examining Authority This first report contains indications relating to the following items: Box No. I Basis of the opinion ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application Certain observations on the international application Box No. VIII The applicant is hereby invited to reply to this opinion. 3. See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e). By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. When? How? For the form and the language of the amendments, see Rules 66.8 and 66.9. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. Also: For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4. If no reply is filed, the international preliminary examination report will be established on the basis of this opinion. The final date by which the international preliminary report on patentability 4. (Chapter II of the PCT) must be established according to Rule 69.2 is: 03.11.2005 Authorized Officer

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# IAP5 Rec'd PCT/PTO 22 DEC 2005

### WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No. PCT/EP2004/007215

		10/562368	10/562368	
	Box No. I Basis of the opini	on		
1.	With regard to the language, this opinion is based on the international application in the language in which was filed, unless otherwise indicated under this item.			
	<ul> <li>□ This opinion is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:</li> <li>□ international search (under Rules 12.3 and 23.1(b))</li> <li>□ publication of the international application (under Rules 12.4)</li> <li>□ international preliminary examination (under Rules 55.2 and/or 55.3)</li> </ul>			
	With regard to the <b>elements</b> of the international application, this opinion is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"):			
	Description, Pages		-	
	1-20	as originally filed	<b>©</b>	
+	Claims, Numbers		S	
	1-15	received on 04.05.2005 with letter of 03.05.2005	À	
ı	Drawings, Sheets	·	A	
	1/4-4/4	as originally filed	Ba	
E	☐ a sequence listing and/or ar	ny related table(s) - see Supplemental Box Relating to Sequence Listing.	E C	
3. [	<ul> <li>☐ The amendments have result the description, pages</li> <li>☐ the claims, Nos.</li> <li>☐ the drawings, sheets figs</li> <li>☐ the sequence listing (specified any table(s)) related to see</li> </ul>	ecify):	BEST AVAILABLE COPY	
4. 🗆	<ul> <li>This opinion has been established been considered to go (Rule 70.2(c)).</li> <li>□ the description, pages</li> <li>□ the claims, Nos.</li> <li>□ the drawings, sheets/figs</li> <li>□ the sequence listing (spe</li> <li>□ any table(s) related to se</li> </ul>			

# WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No. PCT/EP2004/007215

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-15

No:

No:

Claims

Inventive step (IS)

Claims Yes: Claims 1-15

Industrial applicability (IA)

Yes: Claims 1-15

No: Claims

2. Citations and explanations:

see separate sheet

Certain observations on the international application Box No. VIII

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

International application No.

PCT/EP2004/007215

# Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document/s (D) is/are referred to in this communication:

D1: EP-A-0 774 348 (BRAUN MELSUNGEN AG)

## 1. Novelty

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1.1 Document D1, which is considered to represent the most relevant state of the art, discloses sterilisable co-extruded films for wrapping containers for solutions, suspensions, solids or mixtures for parenteral, enteral or stomach tube feeding.

The tube consists of three layers, i.e.

- (a) polypropylene homopolymer (homo-PP, outer layer),
- (b) ethylene vinylalcohol copolymer (EVOH), in particular a copolymer with an ethylene content of 27-38 mole% and
- (c) a single-phase PP homo- or co-polymer (inner layer).

The three layers (a), (b) and (c) have thicknesses of 20-40  $\mu$ m (a), 15-35  $\mu$ m (b) and 30-50  $\mu$ m, respectively; cf. D1, the passages cited in the Search Report, in particular the claims. The material of inner layer (b) is selected to provide the required oxygen barrier properties. It is clear that the ethylene content of the EVOH copolymer is selected to maintain barrier properties during sterilization at 121 °C (cf. p 2/3, bridging paragraph and p 3/I 11-21 and 37).

1.2 The wording of present claim 1 is not clear, since it does not define the matter for which protection is sought (see hereinafter under item VIII).

It appears from the present application that the EVOH material of the intermediate layer of the claimed films corresponds to the material used in D1 (cf. present claim 5). Since the material of the intermediate layer determines the oxygen transmission rate through the film, it is to be assumed that the films according to D1 and the films of the present application have the same properties as regards oxygen transmission rates.

The films according to present claim 1 allow for desorption of water absorbed in the intermediate layer during sterilization, whereas document D1 is silent as regards such

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desorption properties.

The claimed films differ from those according to D1 in the nature of the outer layer (i.e. the presence of a (co)PET outer layer. Thus, the claimed films are novel over the disclosure in D1. The subject-matter of present claims 1-15 therefore appears to meet the requirements of Article 33(2) PCT.

# 2. Inventive Step

The claimed films differ from the most relevant state of the art (D1) in the nature of their outer layer and in their desorption properties (see hereinabove under 1.2). The problem to be solved by the present application may therefore be regarded as to provide multilayer films having a low oxygen transmission rate (i.e. <0.7 ml/m²d) and at the

same time allowing for improved recovery of the gas barrier properties of the core layer after sterilization.

It appears from a comparison of the results presented in Fig. 3 that the presence of an outer layer of PET instead of PP renders the obtainable films more effective in the desorption of water and, thus, improves the long term barrier properties of the corresponding container.

None of the documents of the prior art contains an incentive for the skilled person to combine layers of a saponified polyolefin-vinyl acetate copolymer in combination with layers of a polyalkylene terephthalate resin (e.g. bonded by means of an adhesive) when aiming at structures allowing for improved desorption of water e.g. absorbed during sterilization. Thus, the subject-matter of present claims 1, 12 and 13 appears to meet the requirements of Article 33(3) PCT.

Claims 2-11, 14 and 15 are dependent on claim 1 or 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

# Re Item VIII

Certain observations on the international application

The claims do not meet the requirements of Article 6 PCT in that the matter for which

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protection is sought is not defined.

Claim 1 attempts to define the subject-matter in terms of the result to be achieved, namely the ability to desorb water absorbed in the intermediate layer, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Moreover, neither the claims nor the description appear to specify details concerning a method to determine the ability to desorb water absorbed in the intermediate layer. Thus, the claim is also not clear as regards the definition of the property as such.